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April 9, 2019

VIA FACSIMILE

The Honorable Joel Schneider
United States Magistrate Judge
District of New Jersey
Mitchell H. Cohen Building & U.S. Courthouse
4th & Cooper Streets
Camden, NJ 08101

Re: In re Valsartan NDMA Products Liability Litigation
Case No. 1:19-md-02875-RBK-JS

Dear Judge Schneider:

This letter is to provide Defendants' position with respect to the topics on the agreed agenda for the teleconference with Your Honor on April 10, 2019.[1]

- The parties have met, conferred, and come to an agreement on a proposed Direct Filing Order, which has been filed with the Court (Doc. No. 75).

- Discussions with Plaintiffs' counsel regarding Defendants' proposed Confidentiality Order are ongoing, as are the parties' preliminary discussions regarding the scope of Plaintiffs' Initial Profile forms. Although the details of those discussions are not outlined herein, Defendants will be prepared to provide a status update to the Court on April 10.

[1] Although Defendants take no position with respect to Plaintiffs' leadership, Defendants note that only a subset of those who have sought leadership positions have participated in discussions about the enclosed topics. Defendants look forward to Plaintiffs' update to the Court regarding the composition of Plaintiffs' leadership and related unresolved issues related to the scope of the MDL.

- Defendants did not receive Plaintiffs' ESI proposal until yesterday, and therefore are not in a position to discuss its substance with the Court at this time.

As to the remaining agenda items, as set forth below, the parties require the Court's guidance resolving remaining disputes with respect to: 1) the concept of core discovery and an initial set of documents to be produced; 2) the service of foreign Defendants; and 3) a confidentiality order governing discovery.

I. PERTINENT FACTUAL BACKGROUND

A. The Valsartan Recall and Negligible Risk to Patients.

Valsartan is an angiotensin II receptor blocker ("ARB") that operates by relaxing blood vessels, which lowers blood pressure and makes it easier for the heart to pump blood. The impurities at issue are N-nitrosodimethylamine ("NDMA") and N-nitrosodiethylamine ("NDEA").

NDMA and NDEA are organic chemicals that are the by-product of several biological and industrial processes. They occur naturally in air, water, and soil, as well as in a number of commonly consumed foods, such as cured meats, cheese, beer, and bacon. Thus, the presence of NDMA and NDEA in an ingestible product is not in itself cause for alarm, so long as the quantity and concentration of the impurity falls within acceptable levels.

There is no evidence that the trace amounts of NDMA or NDEA found in some of the recalled products is unsafe or capable of causing injury. On January 25, 2019, FDA Commissioner Scott Gottlieb, M.D., and Janet Woodcock, M.D., Director of the Center for Drug Evaluation and Research, issued a statement "on the FDA's ongoing investigation into valsartan and ARB class impurities and the agency's steps to address the root causes of the safety issues" in valsartan and other ARBs, and noted that:[2]

- NDMA and NDEA are known environmental contaminants found in water and foods, including meats, dairy products and vegetables.

- The risk to patients based on the maximum possible exposure is "very small."

[2] The FDA's statement is available at: https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm629796.htm and attached as Exhibit 1.

- It is unlikely that the potential impurities could have been found on a routine current good manufacturing practice (CGMP) inspection.

- Patients taking any recalled ARB should continue taking their current medicine until their pharmacist provides a replacement or their doctor provides an alternative treatment option.

- FDA scientists estimate that if 8,000 people took the highest daily valsartan dose (320 mg) that contained NDMA, for four years (the time FDA believes the affected products had been on the U.S. market), there may be one additional case of cancer beyond the average cancer rate among those 8,000 Americans.

- The vast majority of patients exposed to NDMA through ARBs received much smaller amounts of the impurity than the worst-case scenario. Since not all ARBs are affected, it's very likely that a patient taking an ARB for four years would not have always received one of the affected products.

Just last week, the FDA "concluded through [FDA's] risk assessments that the maximum possible exposure to nitrosamines (which are also known environmental contaminants and found in water and foods, including meats, dairy products and vegetables) in ARB medicines appears to be small . . . ,"[3] and advised: "Patients should continue taking their medicine until their pharmacist provides a replacement or their doctor provides an alternative treatment option -- even if they learn that their ARB medicine is recalled. The risk associated with abruptly discontinuing the use of these important medicines *far outweighs the low risk that our scientists estimate to be associated with continuing the medicine* until the patient's doctor or pharmacist provides a safe replacement or a different treatment option."[4]

B. The Distinct Roles of Each Category of Defendant in the Valsartan Supply Chain.

Defendants are various entities involved in the distribution of valsartan to consumers in the U.S.:[5] active pharmaceutical ingredient ("API") manufacturers (including API distributors),

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[3] *See* "Statement from FDA Commissioner Scott Gottlieb, M.D., and Janet Woodcock, M.D., director of the Center for Drug Evaluation and Research on the agency's list of known nitrosamine-free valsartan and ARB class medicines, as part of agency's ongoing efforts to resolve ongoing safety issue," April 4, 2019, available at: https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm635251.htm and attached as Exhibit 2.

[4] *Id.* (emphasis added).

[5] Defendants Hetero USA, Inc. and Prinston Pharmaceutical Inc. serve only as FDA liaisons for other entities that fall into the five groups enumerated here.

finished dose manufacturers (including finished dose distributors), third-party distributors, repackagers, wholesalers, and retailers.[6] As seen in Exhibit 3, some Defendants fall into more than one group. Importantly, each of the Defendants, whether at the same level or different levels in the valsartan supply chain, are situated differently. For example, the manufacturing Defendants employed different and proprietary manufacturing processes; not all of the lots of valsartan API or finished doses have been recalled; the levels of the impurities found in the recalled lots differed from lot to lot; and the repackagers, wholesalers, and retailers acquired their valsartan from different manufacturers.

Notwithstanding the impurities' occurrence, if at all, in the manufacturing process of valsartan API , Plaintiffs' claims attack the entire valsartan supply chain.

II. PROCEDURAL POSTURE

As the Court noted during the Initial Case Management Conference on March 27th, Plaintiffs must still come to an agreement regarding a number of foundational issues before this litigation can proceed. For example, in addition to determining the organization of their leadership, Plaintiffs must come to a consensus regarding the scope of this litigation by determining whether they will request that the JPML add claims relating to losartan and irbesartan to this MDL. *See* March 27, 2019 Case Management Conference Tr. at 8:22–9:13, 17:24–22:7, 22:9–22:19 (hereinafter "CMC Tr."). In addition, Plaintiffs have not yet determined the categories of cases for which they will seek to file Master Complaints, and it appears unlikely that Master Complaints will be filed in the next 90 days. Further, multiple foreign Defendants have yet to be served with process in any cases.[7]

Although these threshold tasks have yet to be completed by Plaintiffs, the Defendants have met and conferred with at least some of Plaintiffs' proposed leadership/liaison counsel to address the issues presented in Case Management Order No. 1, paragraph 13, as well as the topics listed in Case Management Order No. 2. While the parties have made progress on a number of issues, and the parties are just beginning the meet and confer process on some topics, current disputes remain as to: core discovery, service on foreign Defendants, and a protective order governing discovery.

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[6] Attached as Exhibit 3 is a chart identifying certain Defendants' role in the manufacture and distribution of valsartan-containing products.

[7] As noted during the Initial Case Management Conference, Defendants remain concerned that they are negotiating discovery requirements that may potentially be imposed on parties that have not yet been served and are not yet represented by counsel.

III. APRIL 10, 2019 AGENDA ITEMS AT ISSUE

A. Plaintiffs Have Not "Sharpened Their Pencils," But Instead Have Issued 22 Requests For Non-Core Discovery That Cover Every Aspect Of Their Claims.

In the parties' Joint Submission of March 20, 2019, Defendants proposed the following discovery from the API manufacturers and finished dose manufacturers as core discovery:

For API Manufacturers:

1. ANDA File
2. The Drug Master File
3. Communications with the FDA relating to the valsartan and/or other ARB recalls
4. Supplement to Drug Master File re manufacturing process approved by FDA in 2012-2013

For Finished Dose Manufacturers:

1. The ANDA file for each involved finished dosage formulation
2. Communications with the FDA concerning the ARB recalls
3. A list of customers to whom each manufacturer sells

Doc. No. 35 at 17-18.

The topics Defendants proposed cover the valsartan manufacturing processes at issue in this case, including all communications with the FDA regarding its investigation, and thus would provide Plaintiffs with the bulk of the most relevant information regarding "how" and "when" any impurities in the recalled valsartan products occurred, as well as "what" the Defendants did upon discovering the potential for impurities. This information is truly "core" discovery. Indeed, it includes *the very information that the FDA is evaluating* in determining how NDMA and NDEA may have occurred in the recalled lots. Further, Defendants' agreement to provide this core discovery prior to raising their defenses under Rule 12(b), including any arguments that this Court lacks jurisdiction over certain Defendants, represents a significant compromise and willingness to cooperate in order to facilitate efficient litigation.

Defendants' proposed core discovery also encompasses many of the categories of information that Plaintiffs identified in the parties' Joint Submission. Plaintiffs initially requested the following categories of discovery:

> the rolling production of defendants' initial disclosures, pursuant to an ESI protocol to be negotiated, including the categories set forth in Rule 26(a)(1), and information sufficient for the parties and the Court to understand the timeline of relevant events, the details of how the contamination occurred, the nature and quantity of the contamination, the distribution process, the quantity and sale prices of the medication, and the identification of each person with relevant knowledge and the

> scope of that knowledge; all beginning with the manufacturing location through to sale in the United States.

Doc. No. 35 at 15-16.

Consistent with Defendants' proposal, Judge Kugler observed during the March 27th Initial Conference that "one of the first questions that [the parties] need focus on is how did this happen. . . . everybody needs to focus on how this happened." CMC Tr. at 3:11–12; 3:22-23. As the Court noted, this focus would also serve to weed out "peripheral defendants . . . who shouldn't be here . . . ." CMC Tr. at 32:23-24. The Court requested that Plaintiffs narrow their approach to reflect the different roles that each Defendant plays in the valsartan supply chain, and to ensure that the correct parties were named as Defendants. *See, e.g.,* CMC Tr. at 7:19–8:8 (suggesting Plaintiffs' counsel consider dismissing Defendants farther down the valsartan supply chain). Nevertheless, and notwithstanding the Court's direction, rather than provide Defendants with specific discovery requests that focus on the "how" of this case and limit the burden on Defendants who do not have information regarding the valsartan API manufacturing process,[8] Plaintiffs instead expanded their core discovery proposal to ***twenty-two*** broad categories directed to ***all*** defendants. *See* April 2, 2019 Ltr. from A. Slater to S. Goldberg, attached as Exhibit 4.

As the Manual for Complex Litigation observes, "[e]arly identification and clarification of issues is essential to discovery control. It enables the court to assess the materiality and relevance of proposed discovery and provides the basis for a fair and effective discovery plan." Manual Complex Lit. § 11.41 (4th ed.). However, prediscovery disclosure "should not place unreasonable or unnecessary burdens on the parties[.]" *Id.* at § 11.13. Rather, in order to be effective, initial discovery should "focus on the core issues in the case to assure that *only the most relevant and important discovery* is produced," and should also serve to narrow the parties and issues in a case so that the parties do not go "down a rabbit hole" at a later stage in the proceedings. *Udeen v. Subaru of Am., Inc.,* No. 18-17334(RBK/JS), 2019 U.S. Dist. LEXIS 40049, at *4-5 (D.N.J. Mar. 12, 2019) (emphasis added).

By failing to direct their requests to the manufacturer Defendants who have information related to the core issues of the case, Plaintiffs' requests unnecessarily include the distributor, repackager, wholesaler, and retailer Defendants that, because of their lack of involvement in the API manufacturing process, do not have information related to the central issues in this litigation. To the extent that distributors, repackagers, wholesalers, and retailers are likely to have any relevant information, it would relate primarily to the identification of the products sold to retail customers, sales data, and prescriptions that were filled. That information is not material at this early stage of the proceedings, which the Court has emphasized should focus on the valsartan API manufacturing process and the manufacturer Defendants' discovery of the impurities found in

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[8] These include the numerous wholesalers, repackagers, and retailers named as Defendants in this case, all of whom are farther down the supply chain, as well as the Defendants who have only recalled losartan or irbesartan products.

valsartan. *See* CMC Tr. at 3:11–12. Similarly, there are currently manufacturers named as Defendants that have only recalled losartan and irbesartan products, and who should not be required to answer any discovery if losartan and irbesartan claims are not part of this MDL.[9]

In addition, rather than focusing on threshold issues that will facilitate the efficient progression of this litigation, Plaintiffs have issued a series of overly broad and vague requests, many of which would be objectionable at any phase of this litigation and are certainly not appropriate for "core" discovery. As an example, Plaintiffs have requested:

> *All* relevant testing of API and finished product going back to *2010*, including testing performed by or on behalf of any defendant, or by another party or entity (including for example customers, regulatory agencies, or any others), and the results, including *any documents analyzing such results*.

(Exhibit 4 at ¶7) (emphasis added). By failing to limit this vague request to specific Defendants, to valsartan (or even to sartans generally), or to a time period that is within the scope of the FDA's investigation (i.e., four years), a response to this request would result in an expansive amount of information, most of which would not be relevant to this litigation. Further, this request ignores the fact that, as the FDA has repeated on many occasions, "NDMA's properties make it hard to detect in standard laboratory testing," and its scientists have just recently "developed and refined novel and sophisticated testing methods specifically designed to detect and quantify the NDMA and NDEA in all ARB medicines." Exhibit 1. In addition, *nine years* of testing information and results, including "all documents analyzing such results," would be impossible to compile in a prompt manner, and the burden on Defendants to collect such information at any stage of the proceedings would be disproportionate to the needs of this case. [10]

Plaintiffs have also requested "[a]ll communications with regulatory authorities relevant to this case, including the FDA, EU, Canada, India, China, and Israel." Exhibit 4 at ¶1. Notably, the valsartan API and finished dose manufacturer Defendants *have already offered* to produce their communications with the FDA regarding the valsartan recalls. Defendants' proposal encompasses

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[9] Even if losartan and irbesartan claims are ultimately included in this MDL, these Defendants should not be required to answer discovery, "core" or otherwise, until the JPML issues an order transferring those cases into this MDL. Further, even if Plaintiffs choose to pursue non-valsartan claims, and the JPML orders them to be included in this MDL, the scope of any discovery should be proportionate to the amount of recalled product, especially when some Defendants have small amounts of recalled product (e.g., as little as a single lot of product, or less).

[10] Even if the parties were at a point in this litigation where this information *may* be relevant, Defendants would object to providing this information on the basis of proportionality, as Federal Rule of Civil Procedure 26(b)(2) directs the Court to limit the frequency and extent of discovery permitted by the rules to prevent discovery for which "the burden or expense . . . outweighs its likely benefit, taking into account the needs of the case . . . the importance of the issues at stake . . . and the importance of the proposed discovery in resolving the issues."

the very information that the FDA is evaluating in determining how NDMA and NDEA occurred in the recalled lots, and *there is no plausible reason why Plaintiffs would need more information than what the FDA has requested on these core issues*. As the JPML made clear in its Transfer Order, the scope of this MDL is limited to U.S. products that were subject to FDA regulation and the 2018 FDA recall, not other foreign agencies. *In Re: Valsartan N-Nitrosodimethylamine (NDMA) Contamination Prods. Liab. Litig.*, MDL No. 2875 at 1-2 (J.P.M.L. Feb. 14, 2019) (transfer order) ("This litigation arises out of an investigation by the U.S. Food and Drug Administration . . ." and "[a]ll actions stem from the same FDA investigation and voluntary recall announced in July 2018"). Even if the parties were engaged in full merits discovery, rather than "core" discovery, to require Defendants to compile all communications with a multitude of foreign regulatory authorities would be entirely disproportionate to the needs of this case, where none of the Plaintiffs in this MDL purchased the products outside of the United States. *See In re Bard IVC Filters Prod. Liab. Litig.*, 317 F.R.D. 562, 566 (D. Ariz. 2016) (where, as here, "there are no Plaintiffs in this MDL from foreign countries," the Plaintiffs "allegedly were injured in the United States," and "the burden of this foreign discovery would be substantial," "the proposed discovery is not proportional to the needs of the case"). Such communications with a multitude of various foreign agencies who had no regulatory authority or involvement with the medications Plaintiffs in this MDL purchased, and which in many instances would post-date the relevant time period, are wholly irrelevant and potentially confusing in this litigation.

Plaintiffs' other 20 requests suffer from similar infirmities by going beyond the scope of the core issues identified by the Court or because they are so vague that it would be unreasonable to expect Defendants to respond. For example:

- Several categories of information in Plaintiffs' proposal are only relevant to Plaintiffs' damages analysis (*see* Exhibit 4 at ¶¶11-17), including a request that Defendants "[d]efine and quantify the [v]alsartan market in the United States" (*id.* at ¶11) and provide "retail and wholesale or bulk pricing, with sales broken down by state and nationally" (*id.* at ¶12). These requests exceed the scope of core discovery by requesting documents that go beyond to foundational issues of standing, jurisdiction, and liability. Indeed, the Court has already recognized the threshold issue of causation will have a spillover effect on each category of case. *See* CMC Tr. at 4:12–16 ("I think that causation carries over into the other cases that are pending because, you know, if the contamination is not dangerous, then maybe you don't have such a great argument that you should get your money back for paying for it.")

- Plaintiffs have also requested "[h]ow, when, why and where the contamination of [v]alsartan occurred" (Exhibit 4 at ¶5). This vague request runs directly counter to the Court's direction in Case Management Order No. 2 that Plaintiffs' core discovery list include "a description sufficient to identify the documents and/or class of documents." *See also* CMC Tr. at 25:5–25 (requesting that Plaintiffs "come

up with" a "reasonable list of core documents," such as documents "available from the FDA anyhow").

Rather than outline the overbreadth of each of Plaintiffs' remaining 13 requests, which is facially apparent (*see* Exhibit 4), Defendants respectfully suggest that the discovery that Defendants have proposed is more than sufficient for the purpose of "core" discovery, and is proportionate to the needs of this case, especially at this very early stage of the proceedings.

B. Plaintiffs Should Be Required to Serve Each Category of Complaint on Each Foreign Defendant in Accordance with the Hague Service Convention.

As a fundamental matter of due process, Defendants insist that service of process be effectuated pursuant to Rule 4 of the Federal Rules of Civil Procedure and that foreign Defendants be served in accordance with the Convention on the Service Abroad of Judicial and Extrajudicial Documents in Civil or Commercial Matters ("Hague Convention"). Indeed, "[s]ervice of process must satisfy both the statute under which service is effectuated and constitutional due process. When the defendant resides abroad, the statutory prong is governed principally by the [Hague Convention], an international treaty that has been ratified by several countries, including the United States and India," *Celgene Corp. v. Distinct Pharma*, No. 2:17-cv-5303, 2018 WL 4251848, at *3 (D.N.J. Sept. 6, 2018), where several Defendants are located, as well as China, *Dartell v. Tibet Pharm., Inc.*, No. 2:14-cv-3620, 2017 WL 1206003, at *3 n.3 (D.N.J. Mar. 31, 2017), where other Defendants are located. "The provisions of the Hague Convention are mandatory; failure to comply voids the attempted service." *Eli Lilly and Co. v. Roussel Corp.*, 23 F. Supp. 2d 460, 470 (D.N.J. 1998) (citing *Volkswagenwerk Aktiengesellschaft v. Schlunk*, 486 U.S. 694, 698 (1988)).

Nonetheless, in an effort to compromise and to avoid unduly delaying the progress of this litigation, Defendants are willing to consider a limited waiver of their otherwise unalienable rights to demand proper service of process. More specifically, Defendants propose that Plaintiffs be required to formally serve each Defendant at least one time with each type of complaint, meaning, for example, Plaintiffs would have to serve an India-based Defendant via the Hague Convention in one personal injury case, one consumer class action case, and one third party payor case. This is consistent with the overall purpose of the Hague Convention, which is "to ensure that judicial and extrajudicial documents to be served abroad shall be brought to the notice of the addressee in sufficient time." *Id.* at 470 (citing Hague Convention, Preamble, 20 U.S.T. at 362). Once Plaintiffs have effectuated formal service of at least one complaint in each category of cases, subsequently filed complaints may be served directly upon Defendants' counsel of record as contemplated by Rule 5(b)(1) of the Federal Rules of Civil Procedure.

C. The Court Should Approve Defendants' Proposed Confidentiality Order.

Defendants prepared and circulated a Proposed Stipulated Discovery Protective Order of Confidentiality ("Proposed Protective Order") to Plaintiffs' counsel on March 26, 2019, the day before the initial Case Management Conference. Plaintiffs initially refused even to look at

Defendants' draft, stating that they would not read any proposed Order that did not originate with the more limited Benicar Order. Ultimately, Plaintiffs agreed to read and provide comments responsive to Defendants' draft, and they even agreed conceptually to adopt certain provisions that were not included in the *Benicar* version. To date, however, Plaintiffs have provided no specific comments to Defendants' proposal.

As a brief aside, Defendants note that while *Benicar* involved a single group of defendants represented by a single law firm, there are currently ***16 separate defense groups*** in this litigation, each represented by their own counsel. Many of the ***nearly 40 entities named as Defendants*** compete directly with one another. Separate law firms represent each of these 16 defense groups. The proprietary interests of numerous, competitor parties simply was not at issue in *Benicar*, and the Protective Order in that matter was not crafted with these interests in mind. Moreover, while *Benicar* involved only personal injury claims, this litigation also includes consumer class actions and claims by third party payors, which may center on sensitive financial information. Finally, the scope of this litigation is still being defined. As the Court acknowledged in asking the parties to address whether losartan and irbesartan products will be included in the litigation and to propose a timeline for raising this issue before the JPML, questions remain about whether manufacturing processes for non-valsartan products will be at issue and whether parties involved in this litigation solely on the basis of non-valsartan products are proper parties to the MDL. Any production undertaken by parties only tangentially involved in this litigation must be done pursuant to a protective order which adequately accounts for their interests and insures their legitimately confidential information will remain protected in the likely event they will be dismissed. Particularly given Plaintiffs' requests for early and extremely broad core discovery on all Defendants, the parties must have a Protective Order in place that protects the interests of the dozens of different types of Defendants involved in this complex litigation.

In light of these distinctions, the Protective Order used during the *Benicar* litigation should not be adopted wholesale for this MDL. Defendants prepared their Proposed Protective Order after review of not only the *Benicar* Protective Order, but also the Appendix S form Discovery Confidentiality Order routinely used by the District of New Jersey and orders used in other complex federal court litigation involving similarly complex defense groups.

Defendants asked Plaintiffs' counsel to review Defendants' Proposed Protective Order and provide feedback on March 26, 2019. To date, Plaintiffs have refused to send any comments, proposed revisions, or substantive feedback to Defendants' Proposed Protective Order. Rather, two weeks later on April 9, 2019, Plaintiffs' counsel sent a competing draft of a Stipulated Discovery Protective Order, which was simply a facsimile of the Protective Order entered in *Benicar* with a different case caption and replacing the name of the product at issue in the introductory paragraph with valsartan. To date Plaintiffs have refused to engage and negotiate in good faith over the terms of a meaningful protective order and have responded that they will only agree to a duplicate of the *Benicar* order and no other.

Defendants prepared their Proposed Protective Order in light of several important issues. Fist, the nature of the defense group requires a two-tiered Protective Order – no such interest existed in *Benicar* where a single group of Defendants were represented by a single law firm. Second, the order entered in *Benicar* allows the de-designation or production of a party's confidential information pursuant to a subpoena without the Court's involvement in the event of inaction by the designating entity. The risk of inadvertent disclosure of confidential information in either of these situations is magnified in litigation that includes nearly 40 distinct entities. These, among other concerns, caused Defendants to prepare their Proposed Protective Order, which was drafted after substantial negotiations among defense counsel and after approval from all of the diverse clients represented among the Defendants.

The protection of Defendants' confidential and competitive information from public disclosure is of legitimate importance to the Defendants. Defendants drafted their Proposed Protective Order with the interests of their individual clients and the particular needs of this litigation in mind. Plaintiffs' proposal makes no efforts to account for any distinctions between this litigation and *Benicar*, and is wholly inadequate to protect the interests of this group of Defendants. Accordingly, the Court should approve and enter Defendants' Proposed Confidentiality Order, or, at a minimum, instruct Plaintiffs' counsel to identify the specific provisions of Defendants' proposed draft that are in dispute and to participate in good faith in a meaningful meet and confer process.

IV. CONCLUSION

Defendants look forward to discussing these issues with the Court during the April 10, 2019 telephone conference.

Respectfully submitted,

Seth A. Goldberg

SAG
Enclosures

cc: Adam Slater, Esq. (*via email, for distribution to Plaintiffs' Counsel*)
Jessica Priselac, Esq. (*via email, for distribution to Defendants' Counsel*)
Lori G. Cohen, Esq. (*via email*)
Richard Smith, Esq. (*via email*)
Clem C. Trischler, Esq. (*via email*)

EXHIBIT 1

FDA Statement

Statement from FDA Commissioner Scott Gottlieb, M.D., and Janet Woodcock, M.D., director of the Center for Drug Evaluation and Research on the FDA's ongoing investigation into valsartan and ARB class impurities and the agency's steps to address the root causes of the safety issues

For Immediate Release

January 25, 2019

Statement

Last summer, the FDA learned and reported that some generic versions of the angiotensin II receptor blocker (ARB) medicines contain nitrosamine impurities that don't meet the agency's safety standards. ARBs, including valsartan, irbesartan, losartan and others, are a class of medicines used to treat high blood pressure and heart failure. Nitrosamine impurities, including N-Nitrosodimethylamine (NDMA) and N-Nitrosodiethylamine (NDEA), are probable human carcinogens. These two substances are known environmental contaminants and found in water and foods, including meats, dairy products and vegetables. But their presence in drug products is not acceptable.

We were deeply concerned when we learned about the presence of these impurities. We immediately undertook a major operation to investigate and to identify the root causes for the presence of these impurities in some ARB drugs, and to work with companies to address the risks that the impurities pose to patients.

Our analysis of NDMA found that the risk to patients based on the maximum possible exposure appears to be small. That doesn't diminish our concern and our determination to find out how these impurities occurred in the first instance. We're committed to implementing measures to prevent these impurities from occurring in the manufacturing process in the future. Our ultimate goal is to ensure that these impurities are not present in finished drug products, or their components (including active pharmaceutical ingredients, or API).

There remains a great deal of public interest in this matter. Today, we want to provide an update on this ongoing investigation and outline the steps we've taken to identify the root causes of the nitrosamine impurities and to prevent a recurrence of this episode in the future. This continues to be an exhaustive effort led by a multidisciplinary team of chemists, toxicologists, physicians, pharmacists, communication specialists, investigators and analytical laboratory staff from across the FDA and in collaboration with global regulators.

While we're still investigating the root causes of the impurities, our ongoing effort has determined that the impurities may be generated when specific chemicals and reaction conditions are present in the manufacturing process of the drug's API, and may also result from the reuse of materials, such as solvents.

This issue surfaced in the summer of 2018, when the FDA was informed that API manufactured by Zhejiang Huahai Pharmaceutical Co. Ltd. (ZHP), in Linhai, Taizhou Zhejiang China for some generic valsartan-containing medicines contained NDMA, posing a potential safety concern.

Since then, the FDA and additional manufacturers of other ARB medicines have identified more cases of NDMA impurities, as well as NDEA impurities. We've placed a ZHP facility on import alert to stop all its API and finished drugs made using ZHP's API from legally entering the U.S. We also issued them a warning letter outlining several manufacturing violations, including impurity control, change control and cross contamination from one manufacturing process line to another. It's unlikely that the subtle problems causing these impurities could have been found on a routine current good manufacturing practice (CGMP) inspection. Nonetheless, our inspections did reveal systemic problems of supervision that could have created the conditions for quality issues to arise.

We've also worked with manufacturers of all ARB medicines to recall any product that poses a risk to patients. Because of the way API is distributed in the supply chain, one source of contaminated API can impact multiple products. As part of this continuing process, last week, we alerted patients and health care professionals to a voluntary recall of one lot of irbesartan and seven lots of irbesartan and hydrochlorothiazide (HCTZ) combination tablets distributed by Solco Healthcare LLC, a Prinston Pharmaceutical Inc. subsidiary. The recall is due to unacceptable amounts of NDEA in the irbesartan API manufactured by ZHP. We will continue to keep the public updated via our **website (/Drugs/DrugSafety/ucm613916.htm)** of all products being recalled. While we acted aggressively to address the issue once we became aware of it, we must also answer the critical question of, why weren't these impurities detected earlier? We've also been asked whether the FDA could have prevented this from occurring if we had done something differently during surveillance inspections in the preceding years.

We want to lay out the many steps we take to mitigate these kinds of risks.

We engage experts in organic chemistry to detect circumstances that can create the risk for these kinds of impurities to be introduced as a by-product of the manufacturing process or changes made in that process. We also work with international regulators to create standards for mitigating the risk of this type of chemical impurity, known as a "genotoxic" impurity. These chemicals, including NDMA and NDEA, are of special concern to global regulators because, unlike most impurities in drugs, they have the potential to cause harm at very low levels. That's why we have robust policies and procedures in place to guard against these risks.

In March 2018, the FDA issued a **guidance (/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM347725.pdf)** for manufacturers that lays out risk assessments that manufacturers can use to evaluate the presence of genotoxic impurities. This is an internationally-harmonized guidance that regulators and industry have agreed to. The FDA reviews information on impurity testing in product applications and when inspecting facilities. Manufacturers must test for known impurities during their manufacturing processes.

We review information about potential impurities that can occur during manufacturing in applications, including requests that sponsors submit to change some aspects of the manufacturing process, which could create new risks. Specifically, our chemists review applications and referenced information to look for steps and changes where risks could be introduced. To implement a risk assessment for any genotoxic impurity, there must be recognition that it can occur in a product's manufacturing. The guidance lays out the conditions under which these risks can occur and steps that manufacturers should take to test for these potential impurities. Now that we've uncovered the risk of nitrosamine impurities in the manufacturing steps involved in ARBs, we'll incorporate the findings into ongoing policy development.

In addition to our policy work, the FDA inspects manufacturing facilities worldwide. Generally during CGMP inspections, we review the records that manufacturers must maintain regarding required impurity testing. However, the impact of this record review depends on manufacturers conducting appropriate tests that are capable of detecting the impurity. Tests are selected based on assessments of what impurities may develop as a result of the manufacturing process. In other words, it generally needs to be recognized that there's a risk of an impurity occurring as a result of a manufacturing process to know the impurity should be tested for.

Our investigation into ZHP's process identified that a change made to the manufacturing process likely led to this impurity, and that the impurity went undetected by global regulators, including the FDA, for a period of time. Before we undertook this analysis, neither regulators nor industry fully understood how NDMA or NDEA could form during this particular manufacturing process. This is troubling to us and we know it's troubling to the public. This concern is appropriate. Among other steps, we need to take actions that would prevent a similar situation from occurring. We are making important strides at understanding how these impurities occurred, mitigating the risk to patients and learning what steps need to be taken to prevent this from occurring again in the future.

One challenge we've faced is that NDMA's properties make it hard to detect in standard laboratory testing – the kind of testing results that are reviewed during a surveillance inspection. In St. Louis, the FDA maintains one of the most advanced pharmaceutical laboratories of any regulatory agency in the world. As soon as we became aware of the presence of nitrosamine impurities in certain ARB medicines, we began collecting samples of all ARB API and medicines marketed in the U.S. to test these products specifically for NDMA. More testing found NDEA, also a probable human carcinogen, in other valsartan products and other ARBs from different manufacturers.

During this time, our scientists have developed and refined novel and sophisticated testing methods specifically designed to detect and quantify the NDMA and NDEA in all ARB medicines. We've shared these tests on our website to help manufacturers and other regulators evaluate these products as well. To determine if ARB medicines contain these impurities, FDA scientists developed three testing methods. These include the **(GC/MS) headspace method (/downloads/Drugs/DrugSafety/UCM618053.pdf)**, the **combined headspace method (/downloads/Drugs/DrugSafety/UCM623198.pdf)**, and the **combined direct injection method (/downloads/Drugs/DrugSafety/UCM623578.pdf)**. These testing methods can be used for evaluating both drug substances (API) and finished drug products.

Medicines that contain NDMA or NDEA above **certain limits (/Drugs/DrugSafety/ucm613916.htm)** (see 12/19/2018 update) pose an unacceptable risk to patients, and ARBs that contain impurities above these levels are being recalled. We've also posted lists of **valsartan (/downloads/Drugs/DrugSafety/UCM615703.pdf)**, **losartan (/downloads/Drugs/DrugSafety/UCM628993.pdf)**, and **irbesartan (/downloads/Drugs/DrugSafety/UCM629626.pdf)** products affected by the recalls. We'll continue to update these lists as new information develops. And we'll continue to work with manufacturers to ensure all affected products are quickly removed from market. We're also working with API makers to ensure that they fix their processes and cease distribution of affected API.

We know patients rely on these medicines. Part of our work throughout this process has been to mitigate and prevent shortages, where possible. Currently, valsartan products are in shortage, and we know that other types of products may fall into shortage soon. That's why the agency has also evaluated safety data for NDMA and NDEA to determine interim acceptable intake levels for these impurities in the ARB class of medicines. While consumers should limit exposure to NDMA and NDEA, these impurities exist in other ingested products, such as some charcoal grilled food items. And so, our goal is to balance the risk of patients ingesting low levels of the impurities (below the interim acceptable levels) for a short period of time with the risk that there is a shortage of certain ARBs, which may impact patients' ability to access the medicine they need. We remind patients taking these medications or any recalled ARB to continue taking their current medicine until their pharmacist provides a replacement or their doctor provides an alternative treatment option. It also is important to know not all ARBs contain NDMA or NDEA, so pharmacists may be able to provide a refill of medication not affected by the recall, or doctors may prescribe a different medication that treats the same condition.

Overall, the risk to individual patients remains very small, although this doesn't diminish the significance of this episode or our concerns. FDA scientists estimate that if 8,000 people took the highest daily valsartan dose (320 mg) that contained NDMA, for four years (the time we think the affected products had been on the U.S. market), there may be one additional case of cancer beyond the average cancer rate among those 8,000 Americans. The vast majority of patients exposed to NDMA through ARBs received much smaller amounts of the impurity than this worst-case scenario. Since not all ARBs are affected, it's very likely that a patient taking an ARB for four years would not have always received one of the affected products. We're still seeking to similarly quantify the risk from NDEA and plan to communicate our findings as soon as possible.

Now that these risks are identified, we're applying what we've learned to the evaluation of similar manufacturing processes where we now know these risks could arise. As part of this process, the FDA has identified specific factors in manufacturing processes that may contribute to the formation and presence of NDMA and NDEA. Through our investigation, we're working to ensure that other manufacturing conditions don't contribute to NDMA, NDEA, or related impurities in finished drug products. We'll use the information we've learned about these impurities when reviewing applications, assessing manufacturing changes and conducting inspections. Now that they are aware that certain conditions result in the formation of nitrosamines, manufacturers using processes at risk for these impurities are expected to test for them to ensure that active ingredients and finished products are free of detectable levels of a nitrosamine impurities resulting in drug products that that are safe for patients.

While the total exposure to these impurities for most patients was small, we are deeply concerned that patients were exposed to this impurity in the first place and that the presence of nitrosamines went undetected for a period of time. The potential for the development of genotoxic impurities during manufacturing processes is an area of intense focus. We'll continue to improve our science and standards for detecting and preventing these risks.

We'll also continue to keep the public informed on our **website (/Drugs/DrugSafety/ucm613916.htm)**, which contains most current information. Patients and providers can also send email to **druginfo@fda.hhs.gov (mailto:druginfo@fda.hhs.gov)** or call 855-543-3784. We're also encouraging submission of any information related to potential side effects to our **MedWatch program (/Safety/MedWatch/default.htm)**.

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

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Related Information

- FDA updates on angiotensin II receptor blocker (ARB) recalls including valsartan, losartan and irbesartan (/Drugs/DrugSafety/ucm613916.htm)
- FDA Newsroom: Q&A on angiotensin II receptor blocker (ARB) medication class investigation (/NewsEvents/Newsroom/ucm629794.htm)

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EXHIBIT 2

FDA Statement

Statement from FDA Commissioner Scott Gottlieb, M.D., and Janet Woodcock, M.D., director of the Center for Drug Evaluation and Research on the agency's list of known nitrosamine-free valsartan and ARB class medicines, as part of agency's ongoing efforts to resolve ongoing safety issue

For Immediate Release

April 4, 2019

Statement

Since we announced our investigation (/NewsEvents/Newsroom/PressAnnouncements/ucm619024.htm) of impurities found in drugs known as angiotensin II receptor blockers (ARBs), used to treat high blood pressure and heart failure, we've been working to thoroughly understand how this issue arose, how we could address and mitigate exposure to this unnecessary risk to patients, and what we could do to prevent these types of impurities from reoccurring in future medications. We know that the discovery of these genotoxic impurities, called nitrosamines, is alarming to patients who expect their products to be free from these types of impurities. And while we've concluded through our risk assessments that the maximum possible exposure to nitrosamines (which are also known environmental contaminants and found in water and foods, including meats, dairy products and vegetables) in ARB medicines appears to be small, their presence in drug products is not acceptable.

Our response to this issue has been comprehensive and constant – an internal working group led by a multidisciplinary team of chemists, toxicologists, physicians, pharmacists, communication specialists, investigators and analytical laboratory staff from across the FDA and in collaboration with global regulators. We've remained steadfast in making sure we minimize risks to patients who rely on these medications, ensure access to safe ARBs or acceptable alternative therapies, and ensure affected medications are removed from the U.S. supply chain. Although we still have more work to do, we're making significant advances in our efforts to protect patients from unnecessary exposure to these impurities.

Today, for the first time since the first nitrosamine impurity was discovered last summer, we're announcing that we so far have identified **40 ARB medications where our assessment concluded they do not contain any known nitrosamine impurities (/Drugs/DrugSafety/ucm634620.htm)**, with the expectation that this number will increase. Our goal is for this information to help health care providers as they consider acceptable treatment options for their patients. Our assessment takes into consideration testing for impurities conducted by the FDA's laboratories, an evaluation of the manufacturing process used by multiple manufacturers of the active pharmaceutical ingredient (API) found in ARB medicines, as well as other information available to the agency from manufacturers and international regulators. We'll

continue to update **this list (/Drugs/DrugSafety/ucm634620.htm)** of nitrosamine-free ARBs as we become aware of additional information and as we progress in our assessments of other ARB medications.

We're also continuing to work with manufacturers to swiftly remove medications from the market if they contain a nitrosamine impurity at levels higher than the **interim acceptable intake limits (/Drugs/DrugSafety/ucm613916.htm)**. Removing the affected medications from the market has led to shortages, and since then we've been working to mitigate and prevent shortages as often as possible. Currently, valsartan products are in shortage, and we know that other types of products have the potential to fall into shortage soon. In anticipation, the agency is not objecting to temporary distribution of specific lots of losartan that contain impurities above the interim acceptable intake limit, for a short period of time. After careful evaluation of safety data and consideration of the benefits and risks to patients, we think it's critical that patients have access to these drugs while impurity-free losartan is manufactured. Our scientists feel that this will not have a meaningful increased risk for cancer over the time it should take to get impurity-free losartan to market. The agency expects many companies will be able to manufacture losartan without nitrosamine impurities and replenish the U.S. supply in approximately six months. We want to reassure patients that we strongly believe the risks, such as stroke, of abruptly discontinuing these important medicines far outweighs the low risk associated with continuing the medications with these impurities.

In addition to the 40 medications listed above, the list also includes other products on the market that remain under evaluation. For these ARBs, although our overall determination is still pending, at this time nitrosamine impurities either have not been detected or are below the interim acceptable intake limits, and the medications can still be distributed.

We'll keep working with manufacturers to eliminate these impurities from the drug supply, but we recognize that we also need to ensure patients who need ARBs have access now.

We're also providing an update regarding steps we have taken to engage drug product and API manufacturers to address nitrosamine impurities in their medications. We recently sent manufacturers and applicants a **letter (/downloads/Drugs/DrugSafety/UCM635125.pdf)** to inform them about factors that can contribute to the formation of nitrosamine impurities during manufacturing (which we understand may be generated when specific chemicals and reaction conditions are present in the manufacturing process of the drug's API) and to reiterate steps they should take to ensure these impurities are not present in any ARB in the future. In addition to these risks, our letter emphasizes the possibility of contaminated raw materials, including and especially solvents and catalysts (particularly when these are reused). Manufacturers should determine whether the raw materials they use to make drugs were recycled, meaning previously used, even if it is not disclosed by their supplier. We also urge manufacturers to be vigilant and ensure that materials they receive from their suppliers are free of nitrosamines, including when they consider new suppliers.

Patients should continue taking their medicine until their pharmacist provides a replacement or their doctor provides an alternative treatment option --even if they learn that their ARB medicine is recalled. The risk associated with abruptly discontinuing the use of these important medicines far outweighs the low risk that our scientists estimate to be associated with continuing the medicine until the patient's doctor or pharmacist provides a safe replacement or a different treatment option. We're closely monitoring the supply of ARBs and will communicate any drug shortages promptly to the public. Today's news, of the certainty and broad number of nitrosamine-free ARB medicines, is another positive step. Health care practitioners should familiarize themselves with alternative medicines that can be used to treat hypertension, heart failure or renal disease in case of shortages.

Despite the very low risks associated with the use of affected ARBs, we fully recognize that these medications can be made without nitrosamine impurities and are working with manufacturers to reach that goal. We'll continue to prioritize our investigation into this ongoing issue, and we'll provide additional updates to consumers, health care providers and industry on our investigation and assessments to ensure patient safety. We'll continue to improve our science and standards for detecting and preventing the development of genotoxic impurities during the drug manufacturing process, and this will remain an area of intense focus in the months ahead.

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

###

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Related Information

- FDA updates on angiotensin II receptor blocker (ARB) recalls including valsartan, losartan and irbesartan (/Drugs/DrugSafety/ucm613916.htm)
- Questions and Answers: Impurities found in certain generic angiotensin II receptor blocker (ARB) products (/Drugs/DrugSafety/ucm626122.htm)

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EXHIBIT 3

Exhibit 3: Defendants' Roles in Manufacture and Distribution of Valsartan-Containing Products	
Defendant	**Role**
Zhejiang Huahai Pharmaceutical Co., Ltd.	Manufacturer, API & Finished Product
Solco Healthcare U.S., LLC	Distributor, Finished Product
Huahai U.S., Inc.	Distributor, API
Prinston Pharmaceutical Inc.	FDA liaison
Teva Pharmaceutical Industries Ltd.	
Teva Pharmaceuticals USA, Inc.	Distributor, Finished Product
Actavis Pharma, Inc.	
Actavis, LLC	
Torrent Pharma, Inc.	Manufacturer & Distributor, Finished Product
Torrent Pharmaceuticals, Ltd.	Manufacturer, Finished Product
Mylan Pharmaceuticals, Inc.	Manufacturer & Distributor, Finished Product
Mylan N.V.	Holding company
Mylan Inc.	Holding company
Mylan Laboratories, Ltd.	Manufacturer, API & Finished Product
Hetero Labs, Ltd.	Manufacturer, API
Hetero USA, Inc.	FDA liaison
Hetero Drugs, Ltd.	
Aurobindo Pharma USA, Inc.	Distributor
Aurobindo Pharma Ltd.	
Sciegen Pharmaceuticals, LLC	Manufacturer, Finished Product (irbesartan)
Camber Pharmaceuticals, Inc.	Distributor, Pass-through
Sandoz, Inc.	Distributor, Finished Product (losartan)
Major Pharmaceuticals	Repackager & Distributor, Finished Product
The Harvard Drug Group, LLC (d/b/a Major Pharmaceuticals)	Repackager & Distributor, Finished Product
Walgreen Co.	Retailer
Throggs Neck Pharmacy, Inc.	Retailer
Wal-Mart Stores, Inc.	Retailer
Rite Aid Corp.	Retailer
CVS Health Co.	Retailer
The Kroger Co.	Retailer

Exhibit 3: Defendants' Roles in Manufacture and Distribution of Valsartan-Containing Products	
Defendant	**Role**
Quality Food Centers, Inc.	Retailer
Harris Teeter, LLC	Retailer
Harris Teeter Supermarkets, Inc.	Retailer
Northwind Pharmaceuticals, LLC	Repackager
AvKARE, Inc.	Repackager
Bryant Ranch Prepack, Inc.	
H.J. Harkins Co., Inc.	Repackager
Nucare Pharmaceuticals, Inc.	Repackager
A-S Medical Solutions LLC	
Preferred Pharmaceuticals, Inc.	
RemedyRepack, Inc.	

EXHIBIT 4

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April 2, 2019

VIA EMAIL
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Dear Seth:

This letter is written in response to your request for us to provide a written list of our core discovery requests, which are directed to all defendants, to the extent applicable to each. This list supplements the lists of materials the defense has already agreed to produce and includes requests for information the Court listed as of primary importance.

1. All communications with regulatory authorities relevant to this case, including the FDA, EU, Canada, India, China, and Israel.

2. The full and complete distribution process from API manufacture to point of sale including information sufficient to describe the process and the role, obligations, and potential liability of all entities along the chain.

3. Identification of all lots entering into the United States, including the size of each lot, identified by API manufacturer.

4. The nature and extent of the contamination, including variations from lot to lot or by other demarcations, if variation exists.

5. How, when, why and where the contamination of the Valsartan occurred.

6. How and when you discovered that the contamination of the Valsartan occurred, and the steps taken in response.

7. All relevant testing of API and finished product going back to 2010, including testing performed by or on behalf of any defendant, or by another party or entity (including for example customers, regulatory agencies, or any others), and the results, including any documents analyzing such results.

8. The manufacturing process from 2010 to the present, and any changes to the manufacturing process at any time, including communications with regulatory agencies relative to the manufacturing process. To the extent the manufacturing process has been changed at any time since 2010, provide the documents regarding why changed, when changed, and all testing or quality assurance reviews, audits, or oversight, and the results.

9. Each defendant's acknowledged quality assurance obligations, including any protocols or internal rules addressing those obligations, and the documentation of the performance of these responsibilities including any audits or evaluations of the manufacturing process, and related testing. In addition, any documentation of Good Manufacturing Practices protocols and compliance efforts, to the extent not overlapping with the quality documents.

10. Evaluation of the health risks posed by the contamination, including internal or other adverse event reporting, and evaluation of issues such as causation of harm, the mechanism of action, consequences, necessary dosages, and duration of use.

11. Define and quantify the Valsartan market in the United States. How many non-contaminated, and potentially contaminated pills sold, dosages of those pills, and the prices charged.

12. Available cost and pricing information, including but not limited to the Average Manufacturer Price (AMP) and National Average Drug Acquisition Cost (NADAC) and retail and wholesale or bulk pricing, with sales broken down by state and nationally.

13. Available price information, and profit information, to the extent not captured by the prior request.

14. Available information regarding payors, including identities, and amounts paid.

15. Available information regarding formulary placement for generic Valsartan and copay or coinsurance amounts paid by Valsartan patients.

16. Any agreements with any retail pharmacy including but not limited to, CVS, Walgreens, Rite Aid, Walmart, including but not limited to all pricing agreements, including those agreements reflecting any price concessions or stocking fees.

17. Any agreements with Wholesalers, including but not limited to Amerisource Bergen, Cardinal Health, or McKesson including but not limited to all pricing agreements, including those agreements reflecting any price concessions or stocking fees.

18. The disposition or storage status of all potentially contaminated pills, including those that have and have not been tested.

19. List of key witnesses/custodians with knowledge of the core information in this litigation, including their employer, positions, years of employment, and description of areas of knowledge.

20. All potentially available insurance policies, as well as other potential assets and sources of funds to satisfy any settlement or judgment in this litigation, and any and all indemnification agreements that may be applicable.

21. All litigation holds and disclosure to the extent any potentially relevant documents, pills, or other evidence have been destroyed.

22. All communications with any third party payer or pharmaceutical benefit manager concerning the safety, efficacy or manufacturing quality of Valsartan.

We assume you will share this letter with your group and provide a response so that we can meet and confer far enough in advance of the call with Judge Schneider, which is scheduled in less than two weeks.

Very truly yours,

ADAM M. SLATER